

September 24, 2001

Office of Special Nutritionals, (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street, S.W. Washington, D.C. 20204



Re: Statement of Nutritional Support Notification

Dear Sir or Madam:

In accordance with 21 U.S.C. § 343 (r) and 21 CFR § 101.93, Mannatech Incorporated, 600 S. Royal Lane, Ste 200, Coppell, TX 75019, hereby submits an original and two copies of it's notification within 30 days of first marketing its product with the statements presented below:

Supplement Brand Name: Glycentials™ Vitamin, Ambroglycin™ Mineral and Antioxidant Formula.

Supplement Ingredients: See attached brochure.

Text of Statements of Nutritional Support: See attached brochure.

Mannatech Incorporated certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the Dietary Supplement Health and Education Act (DSHEA); and that the information contained in this notice is complete and accurate.

Yours truly, Dennie R. Saarkman

Dennis R. Sparkman, Ph.D.

Director Global Regulatory Affairs

Enclosures: GlycentialsTM Brochure

975 0162 LET 8624



Vitamin, Ambroglycin™ Mineral and Antioxidant Formula

The newest member of Mannatech's Optimal Health System is Glycentials™, an antioxidant-rich multivitamin/mineral formula that provides complete vitamin and mineral support for a healthy body. Minerals in Glycentials™ are delivered in a unique glycinated food-mineral matrix, Ambroglycin™, developed by Mannatech. Additionally, Glycentials™ provides antioxidant-rich nutrients to help the body cope with the harmful effects of oxidative stress. The tablets contain no artificial flavors, colors, sweeteners, yeast, sucrose or dextrose.

Other supplements can't compare!

- A balanced food matrix supplement of vitamins, minerals, trace minerals, antioxidant co-factors, and Ambrotose® complex. The best way to get what vour body needs!
- Antioxidant-rich formula combats the effects of toxins, environmental stress, poor diet, and daily physical and oxidative stress-all of which can damage DNA, cells and tissues and lead to cellular aging.*
- Helps recycle and conserve your body's master antioxidant, glutathione.*
- Co-Q10 is important to brain cells, heart cells, gum cells and Vitamin E utilization, regardless of age!*
- Provides critical nutrients depleted by commonly used prescription drugs.*
- No artificial flavors, colors, sweeteners, no yeast, sucrose or dextrose.

Warning: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under six. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Product #129

120 TABLETS

Supplement Facts

Serving Size 2 Tablets

	Amount per	Serving	Dariy Val.
Calories	10		
Total Carbohydrates			<15
Vitamin A (as Dunaliella salina extract	2,500	IU	50°:
[alpha-, beta-carotene, cryptoxanthin,			
zeaxanthin, lutein] in PNC+)			
Vitamin C (as ascorbic acid in PNC+)	250	m:r	4165
Vitamin D (as cholecalciferol in PNC+)	200		50!
Vitamin E (as d-alpha tocopheryl succinate			6671
mixed d-alpha-, d-beta-, d-delta-, d-gamma-tocopherols, and tocotrienols)	., 200	·u	007.11
Thiamin (as thiamine mononitrate in PNC	750	mer -	50%
Riboflavin (as riboflavin in PNC+)	850		504
Niacin (as niacinamide in PNC+)	10		50%
Vitamin B6 (as pyridoxine hydrochloride,		115 mg	200%
	*	118	20071
pyridoxal-5'-phosphate in PNC+)	400		LOGIL
Folate (as folic acid in PNC+)	400		100%
Vitamin B ₁₂ (as cyanocobalamin in PNC+)			200%
Biotin (as biotin in PNC+)	150		50%
Pantothenic acid (as d-calcium	5	mg	50°
pantothenate in PNC+)			
Calcium (as calcium carbonate,	500	ng	501
calcium citrate-malate-glycinate in Ambro	glycin")		
Iron (as iron glycinate in Ambroglycin™)	7.5	ng	41%
lodine (as potassium iodide in Ambroglycii	75	ncg	50%
Magnesium (as magnesium oxide,	2 50	ทย	626
magnesium glycinate in Ambroglycin™)		0	
Zinc (as zinc glycinate in Ambroglycin™)	7.5	nσ	50%
Selenium (as selenomethionine in Ambrogly	rcin') 100	nco	143%
Copper (as copper glycinate in Ambroglyci		ng	50%
Manganese (as manganese glycinate		ng ng	50%
in Ambroglycin")	, ,	''8	30.1/
Chromium (as chromium dinicotinate-glycir	ate 100		84%
	iale 100	ncg	0478
in Ambroglycin™)			E O Ú
Molybdenum (as molybdenum glycinate	37.5	neg	50%
in Ambroglycin™)			
Boron (as boron glycinate in Ambroglycin		ng	
Silica (as silica glycinate in Ambroglycin [™])		ng	1
Vanadium (as vanadium glycinate	25	ncg	L
in Ambroglycin™)			
Ambroglycin™	240	ng	1
Glycinated multiminerals combined with	watercress (leaves), s	pinach (leaves),
green peas (fruit), ginger (root) and Amb	orotose con	iplex (pa	tent pendingi
[naturally occurring plant polysaccharides	including i	reeze-dri	ed aloe vera
gel extract — Manapol® powder].		_	
+Phytonutrient Complex (PNC)	20	ng	1
Acerola cherry (fruit), orange (peel), rice	bran, rose	hips, soy	protein
containing isoflavones			
Inositol	12.5	ng	- <u>- 1</u>
Choline (as choline bitartrate)	12.5		I.
Alpha-lipoic acid	25		- <u>I</u>
Quercetin	5 1		- !-
Coenzyme Q10	4.5 г		- <u>1</u> -
coentyme Q10	4.3 (ug	1
* Percent Daily Values are based on a 2,0	00 calorie	diet.	

Other ingredients: Microcrystalline cellulose, croscarmellose sodium, stearic acid, magnesium stearate, silicon dioxide, dibasic calcium phosphate and pharmaceutical glaze.

> Manufactured for: Mannatech, Inc., Coppell, TX 75019, USA www.mannatech.com

Mannatech™, Glycentials™, and Ambroglycin are trademarks of Mannatech, Inc. Ambrotose® is a registered trademark of Mannatech, Inc. Manapol® is a registered trademark of Carrington Labs., Inc.

he body systems supported by nutrients

- Heart and Circulatory
- Brain and Nervous
- Endocrine (glands)
- Skeletal/Structural
- Immune and Ce li
- Digestive (energy, and detoxification
- · Bones, Teeth and

he main nutrients in Glycentials:

- Important to overall antioxidant and immune system support, absorbing iron, metabolizing cholesterol, assisting circulation and forming antiinflammatory steroids.
- well as both the female and male reproductive systems. Also helps maintain the balance of calcium in the blood and essential for healthy bones and teeth.
- FOR ALEG: Vital for healthy red and white blood cells, RNA/DNA formation, cell division during growth, and energy levels. Also important for circulatory system support.
- Vitarian B_{1.2}: Essential for several enzyme systems and other health factors also affected by folic acid. Helps convert carbohydrates and develop healthy red blood cells.
- Vitamin E: Antioxidant important for a healthy heart, veins, arteries and skin.
- **Selenium:** Antioxidant co-factor. Required for the function of Vitamin E. Important to immune function, antioxidant support, a healthy heart, breast and prostrate health, and helps to retain youthful-looking skin.
- **Zinc**: Important for growth and reproduction, healthy eyes, sense of taste and smell, immune system support and antioxidant co-factor. Important for certain hormones and health of the prostate gland. Plays a vital role in activities of over 200 enzymes.
- **Chromium**: For blood sugar, reduced food cravings and muscle development. (Balanced blood sugar helps control cravings for refined sugars and high-glycemic foods and is essential to brain function and mental alertness without hyperactivity.)
- **Manganese**: Key to enzyme systems that convert carbohydrates, proteins and fats. Required for growth, development and repair of bones and connective tissue. Also important for immune function and nervous system function.
- **Co-enzyme Q10**: Important for antioxidant support, heart health and immune function. Also important to brain cells, gum cells, heart cells and Vitamin E utilization, regardless of age.
- Inositol: Helps metabolize fats and supports brain function.
- **Choline**: Not really a vitamin but considered essential for healthy brain and liver functioning. Also involved in metabolizing cholesterol.
- Alpha lipoic acid: Antioxidant co-factor and helps with blood sugar support.

- Vanadium: Helps support the pancreas (blood sugar level).
- **B-complex vita**: Along with their co-factors found in Glycentials, perform numerous functions, but are generally considered in terms of their effects on energy metabolism and oxygen. Here's a summary of what these B-complex vitamins and their co-factors do:
- **Thiamine** (**B**₁): Essential for conversion of carbohydrates into energy rather than fat, the health of the nervous system and brain function.
- Riboflavin (B₂): Vital for several enzymes necessary for carbohydrate, fat and protein metabolism. Required for energy release.
- **Niacin (B₃)**: Involved in over 40 biochemical reactions. Also important for energy release.
- **Pyridoxine B₆**: For regeneration of red cells, metabolism of protein and amino acids, and processing of blood fats. Also important in supporting the manufacture of several hormones and in brain chemistry balance.
- **Pyridoxal 5-ph**(: : The active coencyme form of B₆. This vital co-factor is involved in many functions of the body including turning harmful homocysteine into healthful cysteine which is key for cardio-vascular health. This can additionally contribute to the production of glutathione. Several amino acid pathways require P5P.
- **Pantothenic aci**: Important for normal tissue metabolism and energy.
- **Biotin**: Essential for metabolizing carbohydrates, fats and proteins.
- **Vitamin A**: Plant-based alpha carotene, beta carotene and lutein—all important for immune support, antioxidant support and healthy eyes. Essential for the growth of new, healthy cells, tissues and gene expression: the health of the eyes and skin; and reproduction.
- Para-aminoben 2 = 1 : An enzyme cofactor and part of the folic acid molecule.
- Calcium: Essential for healthy bones, teeth and skin.
- **Magnesium**: Essential for healthy bones, teeth, muscles and a healthy heart. Essential to making calcium bioavailable. Works with B₆ for brain function and hormone support.
- Molybdenum: Deficiency of this trace mineral can result in sulfite toxicity.